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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/519,372
Filing Date: December 23, 2004
Appellant(s): PRECOPIO, MICHAEL J.

HENRY MILLSON

For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 2/04/08 appealing from the Office action mailed 8/23/07.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct.

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner. Rejection under 35 USC 112 is withdrawn.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

US 2003/0040504	GANS	02-2003
4368207	LOVER	01-1983
6974584	BESSETTE	12-2005
5288483	CARDIN	02-1994
6303581	PEARLMAN	10-2001
6793931	PRECOPIO	09-2004
7292342	PRECOPIO	11-2007
US SN# 10/382188	PRECOPIO	03-2003

(9) Grounds of Rejection

Claim Rejections - 35 USC § 102

Claims 45-48, 50-53, 55-63 are rejected under 35 U.S.C. 102(b) as being anticipated by GANS.

Instant claim 45 is drawn to methods for treating lice, their nymphs & eggs on skin & hair of mammals, by applying a composition free of any pesticide except benzyl alcohol @ 1-50%. The composition is air impermeable & applied in sufficient quantity to completely saturate hair & skin, is left on until most of the lice, nymphs & eggs are killed, & is then removed with water.

GANS applies 0.5-20% benzyl alcohol compositions on hair & skin of people and animals for up to 20 minutes [0107-108], to kill 100% of the ectoparasites, identified as lice and their eggs [0022,0051] and all examples are to human head lice and with repeated applications if needed [0084]. Carriers [0110,0113] inclusive of gels & polyethylene glycol meet those of the instant claims of “- water soluble or dispersible, substantially air impermeable —”, (instant dependent claim 52 is seen to define the substantially air impermeable carrier to be a gel). Benzyl alcohol compositions need not have any other active - see claim 12 and [0015,0098,0099]; claim 11 is a composition for killing ectoparasites comprising an aromatic alcohol & a carrier, “- the composition is substantially free from other active ingredients.” Claim 12 recites “-wherein the aromatic alcohol comprises benzyl alcohol.”

After application for a short time, the compositions are rinsed [0113].

Gans at [0084] shows 80-100% kill of ectoparasites & their eggs, but is silent about nymphs; if all the eggs & ectoparasites are dead, the nymphs that were present would be dead also, as they, too are ectoparasites.

Appellant argues Gans did not kill all forms of lice, did not use Benzyl alcohol exclusively, nor to achieve 100% kill, did not completely saturate the hair, & did not use a suffocating composition.

Instant claims specify no means for one applying the composition to hair & skin to determine whether or not nymphs are present, & killed, so the same benzyl alcohol compositions applied & left on for the same time period as appellants, would provide the same effects. GANS prefers application & treatment to achieve 100% kill of ectoparasites, defined as lice , eggs, & some other forms, mites, fleas,(claim 24) . All examples are to human head lice.

Although GANS provides no explicit instruction to completely saturate the hair & skin of affected areas, the intent to achieve 100% kill with 1 application is clearly the impetus to sufficiently cover, & the time period of coverage of - up to 20 minutes - is inclusive of at least 2 minutes, & 10 minutes, of instant claims 47 & 62.

The compositions preferably are gels, optionally cleansing shampoos; clearly one so applying a treatment formulation would make every effort to work a treatment formulation into the scalp & hair, even if not so instructed. If necessary, applications are repeated; just as in instant claim 48.

Instant claims 55-59 are to various % Benzyl alcohol of between 1-20 % ; all are within GANS 0.5-20%.

Both GANS & appellant recognize the need for repeated application, when less than 100% kill is effected; both apply 1-20% benzyl alcohol at concentrations in formulations of gel carriers, for scalp & hair application to humans & animals, & leave the formulation on long enough to kill most of the lice , then rinse off.

Although GANS does not explicitly state how death occurs, & that each hair & the scalp are to be completely saturated, one being treated for lice would expect to have a thorough application performed, in order to contact & kill all the vermin. Gans applies the same active in the same manner to the same topical target, thus achieves the same results; no lice.

Claim Rejections - 35 USC § 103

Claims 1,3-9,11,13,15,16,18,20-26, 33-36 & 45-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lover 4368207 and Bessette 6974584 and Cardin et al 5288483, in view of Pearlman 6303581.

Instant claim1 is a method for treatment of ectoparasites, their nymphs & eggs, by applying a water soluble or dispersible substantially air impermeable barrier containing an active monohydric aralkyl alcohols @ 1-50% sufficient to provide pesticidal activity by preventing the ectoparasites from obtaining air & is applied to infected areas of hair & skin in a quantity sufficient to saturate both skin & hair completely, leaving the composition until most of the ectoparasites, nymphs & eggs are killed, & removing them & the composition with water. No other active is permitted.

The claimed instant active monohydric aralkyl alcohols, shown by LOVER, are phenyl ethyl alcohol and benzyl alcohol. These alcohols are licicidal, miticidal and ovacidal (Tables I- III) when tested in vitro , as single actives.

LOVER tested alcohols as ovicidal & ectoparasiticial & shows compositions containing 10-40% alcohols are toxic to ectoparasites; mites, lice & ova , depending upon the carrier system employed, & particular alcohol(col. 2, lines 35-48). Benzyl alcohol is effective @ high concentrations, phenyl ethanol @ low (Tables I-III). These 2 alcohols meet the instant claim 9 & 45 constraints. Lover provides carrier examples at column 5 - gels, shampoos.

Lover shows 2 minute exposure, experimental rather than end use application, is effective. Mechanism of action of suffocation, shampooing, rinsing, saturating is not discussed in this presentation of the effects of the alcohols.

BESSETTE utilizes benzyl alcohol, as at least one plant essential oil in gel & shampoo carriers to control human head & body louse (column 2, lines 50-57) resulting in 100% mortality (column 3, lines 61-67) with or without other toxicants(col. 4, top). The application thus must include thorough saturation of hair and scalp, since it must be applied in an amount sufficient to effect the desired action (col. 6, lines 32 - 37).

Actives are at .01-95% (col. 6, top) of compositions. Application of shampoos to hair & scalp @ dosages determinable by the artisan (col. 6, llines32-52) , inclusive generally of 0.001-5% , & up to 20%, by consideration of many factors, when used in a suitable manner (col. 6, lines 28-43). Specific embodiments are of

combination essential oils, although independent use of essential oils is expressed “-one or more-“ @ col. 3, lines 11, with Benzyl alcohol a preferred compound (examples, col. 3, lines 41-43) thus, other actives are not required, & meet the instant claim requirement of free of other actives.

Bessette does not present an array of useful ingredients & carriers one would expect to use in the shampoos, crèmes & films for treating lice, but examples of such lotions, shampoos & treatment compositions for topical application to skin & hair of humans abounds in the art. Cardin & Pearlman exemplify the use of such compositions.

CARDIN kills head lice, utilizing other of the instant formula I compounds, phenyl alkanols, phenyl propanol & phenyl ethyl alcohol (col. 3, lines 33-46) @ 0.25-5% (col. 5, line 53- line 2, col. 6) in lotions, & free of conventional pesticides- these MAY be added (col. 6, LINES 22-25), thus, are not required, & meet the instant claim requirement of free of other actives. Application & rinse off is shown at col. 12, lines 21-line 66 & at claim 12; the applied licide composition is worked into the hair & scalp, left for 6-10 minutes, & rinsed off.

CARDIN' S compositions do use cationic surfactants as the pediculicide/ovicide, with the phenyl alcohols as synergizers. The reference provides the compounds as instantly claimed as film formers, surfactants & gelling or thickening agents, as seen in examples, particularly of conditioners, and as the gums & polymers at the last paragraph of column 11.

PEARLMAN also treats ectoparasites of man, as alternatives to lindane, malathion & pyrethroids (col. 4, lines 39-43) with barrier compositions that suffocate lice (col. 7, lines 53-63) by triggering an immersion reflex. Various regimens are described, all are applied to hair & skin & then

washed off(col10, lines 57-67, col. 11, lines 9-16). Agents used are surfactants (col. 11, lines 51-57). Various adjuvants common to the cosmetic/pediculicidal arts, but not with toxicants, are disclosed @ col 11-13, & would be obvious & within the purview of the artisan to apply as desired.

The instant actives, phenyl C 2-6 alkanols ,are mentioned as solvents (col. 13, lines 31-33). Thickeners, gums, can be used(col. 13, lines 56-60).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made desiring to utilize ectoparasites pest control means, to use any of art recognized means, as of Lover, Bessette, Cardin or Pearlman modified as desired to increase pesticidal efficacy without irritation or side effects,to increase stability, dispersibility,compatability of ingredients,& reduce toxicity to people infested.

The artisan would readily select the instant aralkyl alcohol, as benzyl or phenyhl ethyl alcohol shown effective by Lover & Bessette to provide a high rate of kill of both lice & their ova, when applied to hair & scalp at 1-20% of a carrier composition of shampoo, film or gel, to permit retention for a 20 minute period before being washed off, as shown by Cardin also using the instant formula I aralkyl alcohol to kill lice.

Regardless of the particular agent used, the phenyl ethanol or Cardin or benzyl alcohol of Lover/Bessette, treatment for lice is shown by Pearlman to consist of application to the hair & scalp of a composition by thorough wetting of hair & scalp, leaving in place for a few minutes, rinsing off, & repeating if needed.

The instant actives are disclosed; the instant methodology is art recognized, & illustrated in the references.

Appellant has not provided any objective evidence of general efficacy of formula I compounds, other than benzyl alcohol, as providing nonobvious or unexpected results.

Appellant has not provided any objective evidence that the administration of the particular ingredients' or concentrations provides any greater or different level of prior art expectation as claimed. The instant invention provides well known old art recognized ectoparasitidal & ovacidal compounds, benzyl alcohol & phenyl ethyl alcohol, applied by well known art recognized methods, shampoo, film former & gel application, left on for a period of time, & washed off, to achieve improved ectoparasite control, killing lice & their eggs, particularly of lice in humans.

APPELLANT'S ARGUMENTS have been fully considered but they are not persuasive. They are to the effect Lover does not provide all of the elements & conditions to kill lice & ova that the instant invention has presented; however, examiner finds the instant claims are broader than the scope argued, & Lover is a directive for alcohol use for ectoparasites control, with expectation of incorporation in known methods with known adjuvants & vehicles common in the lice control arts. These are shown at the secondary references, also directed at lice control, & obvious to the artisan.

In essence, appellant's arguments are that the compositions are either of the generic monohydric aralkyl alcohols of claim 1, , or of the benzyl alcohol of claim

45, & free of other active pesticides. The compositions are applied in a quantity to completely saturate both hair and skin, and result in unobvious effects; a high rate of kill (99-100%) compared to 89% without complete saturation. Appellant also finds the prior art fails to teach killing by suffocation, by applying air-impenetrable composition, the mechanism of action of the instant methods. The prior art is also stated to not teach application of benzyl alcohol applied for a sufficient time and amount to keep breathing tubes open to permit suffocation.

Appellant contends the prior art cited requires more than 1 active, fails to completely saturate hair and skin, and fails to show air impermeable compositions causing death by suffocation.

Examiner finds that Benzyl alcohol or phenyl ethyl alcohol, is utilized by all the cited references in providing compositions for application to skin and hair of animals and people to kill head and body lice and ova, and other ectoparasites.

.Examiner also finds the references, particularly PEARLMAN describes formulations free of air, functioning by suffocation, with mention of the time periods for application, the removal by rinsing with water, and the re-application when needed to provide eradication.

Examiner finds the use of the monohydric aralkyl alcohol or benzyl alcohol in methods for topical treatment of ectoparasites, nymphs, and eggs to be known. Specific compositions of the benzyl alcohol, although presented in the declaration, are only functionally claimed; we see the prior art as providing these compositions, for example as gels, since the prior art (BESETTE for example), also achieves 100% kill. We would expect that although nymph death is unstated, the application to the skin and hair would result in treatment of whatever was there-

nymphs, eggs, and adult ectoparasites/lice. We would expect the artisan, as stated in Cardin & Pearlman, to apply the compositions as completely covering and thoroughly as possible coating all affected hair and skin; failure to achieve complete kill triggers re-application. These are seen as normal expected steps in the process of treating ectoparasite infestations. The benefits we see of thorough coating is not surprising, just tedious, but inescapable if eradication is desired. The prior art shows the instant methods of applying benzyl alcohol or analog in gel and other carriers for coating hair and skin, with achievement of high mortality of lice and other ectoparasites.

Double Patenting

Claims 1, 3-5, 8, 9, 13, 18, 20, 22-26 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 28, 29, 31-38 of Patent No. 6793931.

Although the conflicting claims are not identical, they are not patentably distinct from each other because methods of the patent differ from the instant only in recital of who is treated; the patent treats lice, one of the unclaimed species of ectoparasites of the instant. Nymph and eggs are not specified in the patent, but since the same composition is applied, and left on for 10 minutes until the lice have been suffocated, one in the art would find the nymphs and eggs also pesticidally affected, since they are where the composition is applied. The amounts and concentrations applied would have been obvious; sufficient amount would be required to provide killing of the lice by suffocation (B of claim 28) to

meet the instant 1-50% applied, & left on until the ectoparasites are dead of suffocation. Patent claim 36 limits claim 28 to 1-25%, Claim 37 to 2-25%, thus meeting the amounts of instant claim 1 & dependent claims 22-26.

Dependent claims recite the conditions also recited in dependent claims of the patent. Appellant's arguments to the effect that nymph and eggs are not necessarily treated are not persuasive; application for at least 10 minutes and until lice are dead of the suffocating composition claimed is exactly as the instant one is claimed & would also kill nymphs and eggs, whether or not the artisan knew it.

Appellant's arguments for complete saturation in the instant application; except by time of application, which is met by the patent, is undefined. The declaration of 6/04/07 shows improvement when more material is applied to skin and hair, but 70% still meets the instant claim to providing pesticidal activity, to most of the ectoparasites (most being over 50%). Appellant states that at study 2, the hair was completely saturated. However, it is unclear why one would apply a spotty application of a composition if one knew lice, fleas, tick or nymphs or eggs thereof were present. Further, if the treatment did not completely rid one of lice, it would be self-evident to the applicator to re-apply more carefully, to thoroughly coat the hair and skin. Claim 20 is obvious over patent claim 38.

The patent, while prima facie obvious over the instant claims, does not anticipate them because the recitation of complete saturation is absent.

Claims 1, 3-6, 8, 9, 13, 15, 16, 18, 20, 22-26 & 33 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 33, 35-38, 44-46, 49-51, 65-67, 69-81 of US application # 10/382188.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods differ only in recital of : 1) who is treated; the 519' treats ectoparasites & their eggs & nymphs generally @ claim 1, & Lice & eggs (nits) at claim 45; & in recital of 2) complete saturation @ claims 1 & 45 of 519'; & in recital of 3), leaving the composition until most of the eggs , nymphs & parasites have been killed @ claims 1 & 45 of 519'. The '382 claims are to only killing lice & some of the nits , as in the '519, by suffocation, but no mention is made of nymphs..

Since the same composition is applied , and left on for at least until the ectoparasites or the lice have been suffocated, one in the art would find the nymphs and eggs also pesticidally affected, since they are where the composition is applied.

The amounts and concentrations applied would have been obvious; sufficient amount would be required to provide killing of the ectoparasites or lice, & 519' applies 1-50%. It would have been obvious to one with ectoparasites, whether of known species or not, to apply the ectoparasiticidal formula (I) alcohols & leave it on long enough to kill, lice & nits & also nymphs, fleas, mites or what have you. The result of the use of the '382 methods would be the death of the infesting ectoparasites, their eggs, & nymphs.

Dependent claims recite the times of exposure , conditions & times of repeat application & the concentrations of the active monohydric aralkyl alcohol , and in claim 65 & dependent claims,benzyl alcohol, and specification of the gel forms of

the compositions. Repeat application is shown @ claims 15,16,48 & 49 , & met by dependent claims 76- 81 of '382.

The instant claims are obvious, as one with lice would be motivated to apply a composition designed to rid one of ectoparasites, or lice (claim 45) of '519, and in the process, also destroy any nymphs, eggs, and other ectoparasites, if present.

Claims 1, 3-5,8,9,11,13,15, 16, 18 & 20 are now rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5-13, 15, 16 of US 7294342, formerly rejected as copending Application No. 10336457. Although the conflicting claims are not identical, they are not patentably distinct from each other. As above, the instant claims are obvious, as one with lice would be motivated to apply thoroughly a composition designed to rid one of lice, and in the process, also destroy any nymphs, eggs, and other ectoparasites, if present.

Note the patent claims benzyl alcohol, at 1-50%; the instant alcohol. The patent claim 2 provides the instant claim 13 gel, and so a gelling agent (instant claim 20) must be present. The time periods of patent claim 3 encompass instant claims 3-5. Instant claim 18 is obvious over patent claim 5, & Patent claims 15 and 16 would meet instant claims 15 and 16.

Appellant's arguments for "complete saturation" in the instant application; except by time of application, which is met by the patent, is unspecified in the claim. The declaration of 6/04/07 shows improvement when more material is applied to skin and hair, but 70% kill still meets the instant claim to providing pesticidal activity to most of the parasites (most being over 50%).

(10) Response to Argument

In essence, appellant's arguments are that the compositions either of the generic monohydric aralkyl alcohols of claim 1, free of other active pesticides, or of the benzyl alcohol of claim 45 are not in the prior art; Other actives are permitted. Appellant also states none of the prior art appreciate the need to apply a quantity to completely saturate both hair and skin, thus the instant claims result in unobvious effects; a high rate of kill (99-100%) compared to 89% without complete saturation. Appellant also finds the prior art fails to teach killing by suffocation, by applying air-impenetrable composition, the mechanism of action of the instant methods. The prior art is also stated to not teach application of benzyl alcohol applied for a sufficient time and amount to keep breathing tubes open to permit suffocation.

Examiner finds the use of the monohydric aralkyl alcohol or benzyl alcohol in methods for topical treatment of ectoparasites, nymphs, and eggs to be well-known. Specific compositions of the benzyl alcohol, although presented in the declaration, are only functionally claimed; we see the prior art as providing these compositions, for example as gels, since the prior art (BESETTE for example), also achieves 100% kill.

Gans claims (claim 17) that EACH of the actives present, is present in amount effective to kill the ectoparasites. Claim 12 is a mode of the Gans invention in which only the benzyl alcohol is present. We would expect that although unstated,

the application to the skin and hair would result in treatment of whatever was there-nymphs, eggs, and adult ectoparasites/lice. We would expect the artisan, as stated in the cited references, to apply the compositions as completely covering and thoroughly as possible coating all affected hair and skin; failure to achieve complete kill triggers re-application. These are seen as normal expected steps in the process of treating ectoparasite infestations. The benefits we see of thorough coating is not surprising, just tedious, but inescapable if irradiation is desired. The prior art shows the instant methods of applying benzyl alcohol or analog in gel and other carriers for coating hair and skin, with achievement of high mortality of lice and other ectoparasites.

For the above reasons, it is believed that the rejections should be sustained.
Respectfully submitted,

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